

**Remarks**

Claims 1-28 are pending, including new claim 29. Claims 1, 22-25 and 27- 29 are in independent form.

**Allowable Subject Matter**

Claim 27 is allowed. Claims 6-7, 11-14, 16-21, 25 are objected to as being dependent upon a rejected base claim, but have been found to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

In a September 1, 2010 telephone discussion with the Examiner, attempting to arrange an interview, Attorney for Applicants, Lawrence Sewell, asked the Examiner to clarify the status of independent claim 25, which was grouped with the dependent claims said to be allowable under the conditions described immediately above. The Examiner said that claim 25, being independent, is indeed allowed.

Allowed claim 17 is amended for consistency with amendments to claim 1, on which claim 17 ultimately depends.

An amendment made to allowed claim 25 in the just previous response is reversed in this response, returning the claim to the exact form in which it was determined to be allowable.

Claim 26 is amended to depend on allowed claim 25; hence, it is submitted to be allowable.

In the Final Rejection, there was a Drawings objection related to the phrase "resilient biasing mechanism". Although it was intended that the just-previous response amend the claims to remove this phrase, the phrase was found to remain in claim 28. Claim 28 is amended herewith to remove the phrase.

**Claim Rejections - 35 U.S.C. 102**

Claims 1-5, 8-10, 15, and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Gramnas (6,302,918).

Claim 1 has the following elements not found in Gramnas. Inserted paragraph numbers are references to the elements in paragraphs of the published application.

(1.1) "axial rotation fail-safe mechanism [0043] for... preventing said torque at any level greater than a predetermined threshold safe level from being transmitted by the limb to the bone implant", and similarly

(1.2) "resilient means [0011] for... decoupling ... and by said decoupling for permitting axial rotation of the components in relation to each other for any level of torque greater than said predetermined threshold safe level", and

(1.3) "resilient means for...decoupling the components automatically only when the torque is greater than said predetermined threshold safe level, thereby being sufficient to overcome the maximum effect of the resilient means."

Regarding elements (1.1) and (1.2), in Gramnas, increasing force causes some rotation between outer and inner telescopic parts 10 and 11, but as the force increases further, once resilient member 19 reaches a limit of flexing, there is no additional rotational movement, and any additional increase in force is transmitted to the limb of the patient. For a transcutaneous bone implant, this can result in either breaking the bone or cause the bone implant to become detached from it. This is the very result against which the present invention provides a safeguard ([0003] of present published application).

Gramnas states at column 3, lines 14-21, "At a torsional force right-left the resilient member 19 is compressed and admits depending on elastic stiffness and torsion force a rotation of between 0-30 degrees with a gradually increasing resistance."

By contrast, the present application discloses and claims (element (1.1)) means for decoupling proximal and distal components so that any level of force above the threshold level is decoupled and can not be transmitted to the bone implant.

Furthermore, whereas the Gramnas rotation reaches a stopping point, the present application describes and claims (element (1.2)) means for permitting axial rotation of the distal and proximal components with respect to each other for any level of force. This provides the protection from excessive force being transmitted to the bone implant.

Regarding element (1.3), Gramnas allows rotation only below the maximum effect of its resilient member 19. The present application describes and claims resilient means for “holding the components in fixed relation to each other” until the torque becomes sufficient to overcome the effect of the resilient means and decouple the proximal and distal components, at which point, the resilient means exercises no greater effect in holding the components fixed in relation to each other. The effect of the resilient means has reached its maximum at decoupling.

Thus, the claimed invention has different elements than Gramnas, which allow it to achieve a failsafe result which Gramnas cannot achieve, namely, “protection of the bone implant from the effect of said torque at any level greater than said predetermined threshold safe level”, as stated in claim 1.

For the reasons given, it is submitted that claim 1 as amended is not anticipated by Gramnas and that neither are claims 2-5, and 8, since they are dependent on claim 1.

New independent claim 29 is similar in structure to claim 1 but is directed to the failsafe structure of the invention which protects the bone implant against excessive bending force.

Inspection of the Gramnas reference reveals the following distinct elements in claim 29.

(29.1) “resilient means for... disengaging [0016, 0019]...and by said disengagement for permitting tilting of the components away from said fixed angle relationship for a level of bending force greater than said predetermined threshold safe level, and similarly

(29.2) “disengageable connector [0015] for...preventing said bending force at a level greater than a predetermined threshold safe level from being transmitted by the limb to the bone implant”, and

(29.3) “resilient means for...disengaging the disengageable connector automatically only when the bending force is greater than said predetermined threshold safe level, thereby being sufficient to overcome the maximum effect of the resilient means.”

Regarding element (29.1), Gramnas teaches oppositely from the claimed element, namely that its device is so constructed as to prevent tilting. In Gramnas column 4, lines 32-36, it is stated, “In the damper according to the invention there is provided an automatic mechanical counter movement which counteracts such an obliquity and which creates a force which all the

time strives for maintaining the largest bearing surfaces of the inner telescopic member 11 in parallel.

Regarding element (29.2), it is submitted to be apparent that there is no element of Gramnas that does anything to prevent a bending force from being transmitted by the prosthetic limb to a bone implant, as recited in claim 29.

Regarding element (29.3), in view of the Gramnas teaching to prevent tilting and maintain parallel surfaces, it is submitted to be apparent that there is not means for disengaging when a bending force is sufficient to overcome the maximum effect of a resilient means.

Furthermore, Claim 29 is directed to a failsafe apparatus for attaching a prosthetic limb to a transcutaneous bone implant through the skin directly to the bone of a patient. Such transcutaneous bone implants serve as a stable attachment for attaching an external prosthesis directly to a patient's bone. However, there is a risk that if a patient falls and a large bending force is exerted on the external prosthesis, this would be transmitted to the patient's bone, resulting in either the bone breaking or the bone implant becoming detached from the bone tissue. Gramnas discloses a shock absorber for an external leg prosthesis wherein the leg prosthesis has a hollow socket in which the patient's limb stump is received. As explained above, there is no element in Gramnas that does anything to prevent a bending force from being transmitted by the prosthetic limb to a bone implant (in fact there is no bone implant disclosed in Gramnas). If a very large bending force were applied to the leg prosthesis of Gramnas, tending to tilt it away from the patient's limb stump, the socket of the leg prosthesis would most likely detach from the patient's limb stump, leaving the patient's limb stump undamaged. Therefore the apparatus disclosed in Gramnas could not be used as a failsafe apparatus for preventing a bending force from being transmitted by the prosthetic limb to a transcutaneous bone implant that is attached through the skin directly to the bone of a patient, as recited by Claim 29.

For the reasons given, it is submitted that new claim 29 is not anticipated by Gramnas and that neither are claims 9-10, and 15, since they are dependent on claim 29.

The following Remarks are largely repeated from the just-previous Response.

Claim 28 recites a coupling body coupling both tilting and an axial rotational articulation. As discussed just above in connection with claim 29, Gramnas teaches preventing tilting, so the

reference is submitted not to teach such elements of claim 28 as “resilient biasing means for applying a biasing force holding one of the components engaged with the other component for normal use of the prosthetic limb subject to an applied force less than a predetermined threshold safe level... and only when said force applied to the limb exceeds a said threshold safe level and thereby becomes sufficient to overcome the effect of the biasing force...allows the components automatically to become disengaged and thereby to move in said tilting... articulation”. For this reason, it is submitted that claim 28 is allowable in view of Gramnas.

Claim 22, claiming “an automatically disengageable connector...allowing the proximal and distal components to disengage with freedom to tilt away from the fixed angle relation when, in use, a bending force is applied to the prosthetic limb only when the applied bending force exceeds the predetermined threshold level” is submitted not to be anticipated by Gramnas for the same reason as claims 28 and 29 discussed just above.

Claim 23 describes the “clutch-like mechanism” with faces held in engagement against each other to rotationally couple them and that they are disengaged allowing rotation only upon application to the limb of a force that exceeds a predetermined threshold. It is submitted that Gramnas does not describe such a clutch-like mechanism and engagement and disengagement of the faces. In addition, the claim describes “adjustment means” for increasing or decreasing the predetermined threshold. Accordingly, it is believed claim 23 is not anticipated by Gramnas.

Claim 24 recites “a screw adjustment”. It is submitted that this cannot be read on Gramnas exchanging one resilient member 19 for another. Accordingly, it is believed claim 24 is not anticipated by Gramnas.

For the reasons given, it is submitted that that claims 1-5, 8-10, 15, 22-24, 28 and new claim 29, all as may be amended, are not anticipated by Gramnas.

Further, it is submitted that claims 6-7, 11-14, and 16-21, indicated to be allowable if in independent form, are allowable as dependent ultimately on either claim 1 or 29.

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Weddendorf (5,314,500).

Claim 22 as previously amended makes clear that disengagement of the proximal and distal components with freedom to articulate is the result of a disengageable connector activated

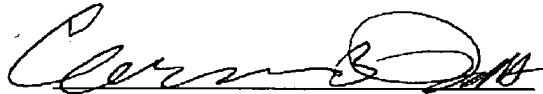
by the effect of a biasing force being opposed by an applied bending force urging the limb toward a tilting articulation. It is submitted that this is not disclosed or suggested by Weddendorf and is not anticipated by the possibility of Weddendorf pin 66 breaking.

Conclusion

In view of the above amendments and remarks, allowance of all pending claims is respectfully requested.

Applicants request to interview the Examiner after he has reviewed the present Supplemental Amendment, and he is requested to call V. Lawrence (Larry) Sewell, who is the author of this Amendment and is of Counsel to Attorney for Applicants, at (214) 349-8180.

Respectfully submitted,



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